Customėr No.: 26021

PATENT 2036-039 (81841.0177)

REMARKS/ARGUMENTS

Minor changes are made to this specification. Claims 3, 12, and 30 are canceled without prejudice. Claims 1, 4, 5, 10, 13, 14, 17, 18, 21, 29, 31, 32, 35, and 36 are amended. Claims 1, 2, 4-11, 13-29, and 31-36 are pending in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Objections:

The Examiner required the specification to be amended by including a section entitled "Brief Description of the Drawings." Applicants disagree with this requirement because the specification as filed containes such section. In this regard, applicants respectfully draw the Examiner's attention to page 7, lines 18-24. Thus, applicants request withdrawal of this objection.

The Examiner noted that the structure of 3-dimethylamino-2-methylpropyl chloride in Figure 1 is missing a hydrogen. In response, applicants amended Figure 1 by adding the missing hydrogen as shown in red.

The Examiner requested the abstract to be amended by including the specific types of the additive claimed in the application. In response, applicants amended the abstract to include the specific types of additives of the present invention.

Claim Rejection Under 35 U.S.C. § 112:

Claims 1-3, 6-12, 15-21, 24-30 and 33-36 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out an distinctly claim the subject matter. In particular, the Examiner rejected the claims for using the term "substituted alkyl." This rejection is most due to the amendments to the claims. The amended claims do not contain the objected term.

Claim 3 is rejected because N,N-dimethylguanidine of claim 3 has a structure different than the base claim 1. This rejection is most due to the cancellation of claim 3.

Claim Rejections Under 35 U.S.C. § 102(b) and §103(a):

Claims 1-3, 5-12, 14-21, 23-30, and 32-36 are rejected under 35 U.S.C. § 102(b) and § 103(a) as being unpatentable over Ito *et al.*, U.S. Patent No. 5,486,479 (the '479 patent) or Ito *et al.*, U.S. Patent No. 5,506,151 (the '151 patent). These rejections are most with respect to claims 3, 12, and 30 due to the cancellation of the claims. With respect to claims 1-2, 5-11, 14-21, 23-29, and 32-36, the rejections are respectfully traversed.

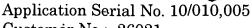
The independent claims 1, 10, 21, and 29 have been amended by adding a limitation that requires an additive comprising a compound selected form the group consisting of triethanolamine, trimethanolamine, N-butyldiethanolamine, 3-dimethylamino-2-methylpropyl chloride, N,N-dimethylglycine, N,N-dimethylglycine, N,N-dimethylglycine ethyl ester, 3-dimethylaminopropionitrile, and N,N-dietylacetamide. This amendment is supported by the original claims 3, 12, and 30, as well as, example on pages 15-20 of the specification.

Neither the '479 patent nor the '151 patent teaches such an additive. The close transition "consisting of" of the instant claims 1, 10, 21, and 29 excludes compounds other than those listed in the group. Dimethylaminopropylamine compound of the '479 and the '151 patents, which is referenced by the Examiner, is not listed in claims 1, 10, 21, and 29. Thus, dimethylaminopropylamineit does not make the claims of the present invention unpatentable.

Also, the Examiner appears to believe that the additive comprising 3-dimethylamino-2-methylpropyl chloride is described in column 3 of the '151 patent. Applicants disagree with such reading of the '151 patent. The '151 patent describes a compound of the following general formula:

$$R_1$$
 N—(CHY)m—(X)n—(CHY)p— R_3

The Examiner states that the above formula of the '151 patent is an equivalent of dimethylamino-2-methylpropyl chloride claimed in the present invention when R_1 and $R_2 = -CH_3$, $(CHY)m = -CH_2$ -; and $(CHY)p-R_3 = -CH(CH_3)$ -



Customer No.: 26021

PATENT 2036-039 (81841.0177)

CH₂Cl. Granted, substitutions suggested by the Examiner (assuming also that n=0) will result in dimethylamino-2-methylpropyl chloride structure:

However, (CHY)p-R₃ of the '151 patent cannot be -CH(CH₃)-CH₂Cl. According to the '151 patent, Y is H, OH, or halogen (column 3, lines 26-27) and, thus, CHY could be -CH₂-, -CH(OH)-, or -CH(Halogen)-, but not -CH(CH₃)-. Also, assuming p=0, R₃ cannot be CH(CH₃)-CH₂Cl. According to the '151 patent, R₃ is -NR₁R₂, -NH₂, -CH₂Y and HCl salts thereof (column 3, lines 28-36). Y is H, OH, or halogen (column 3, lines 26-27) and, thus, CH₂Y could be -CH₃, -CH₂(OH), or -CH₂(Halogen)-, but not -CH(CH₃)-CH₂Cl as proposed by the Examiner. Therefore, the '151 patent does not describe an additive comprising dimethylamino-2-methylpropyl chloride. Thus, the '479 and the '151 patents do not anticipate the present claims 1, 10, 21, and 29.

The '479 and the '151 patents do not suggest the independent claims 1, 10, 21, and 29. Nothing in the '479 patent or the '151 patent teaches or suggests any of the compounds of claims 1, 10, 21, and 29, much less the use of such compounds to reduce non-specific aggregation of particles in particle-enhanced assays. As demonstrated in the example on pages 15-19 of the instant specification, the additive of the present invention comprising one of the specific compounds listed in claims 1, 10, 21, and 29 effectively reduces aggregation of particles in particleenhanced assays.

Additionally, as explained on page 15, lines 14-20, of the instant specification, the methods of the present invention, which utilize the additives listed in claims 1, 10, 21, and 29, unlike conventional methods for reducing non-specific aggregation, are effective at low concentrations of the additives. For example, additive concentrations as low as 0.2M are effective in substantially reducing non-specific Furthermore, unlike additives known in the prior art, the additives aggregation. disclosed in the present invention are inexpensive, and do not require further Customér No.: 26021

PATENT 2036-039 (81841.0177)

processing in order to be effective. Therefore, the possibility of inadvertently using a partially treated additive is eliminated. This is an improvement over the use of other additives such as urea additives described in the '151 patent, since the synthesis of the ureas requires processing large amounts of the hazardous and relatively expensive carbodiimide precursor.

Since unexpected results obtained in the present invention, a mere description of chemically different additives in the '479 and the '151 patents does not make claims 1, 10, 21, and 29 obvious. Therefore claims 1, 10, 21, and 29 are patentable over the cited references. Claims 2, 5-9, 11, 14-20, 23-28, and 32-36 depend from claims 1, 10, 21, and 29, and, thus, they are patentable over the cited references for at least the same reasons as claims 1, 10, 21, and 29.

Applicants thank the Examiner for indicating that claims 4, 13, 22, and 31 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. However, since claims 4, 13, 22, and 31 depend from claims 1, 10, 21, and 29, respectively, and claims 1, 10, 21, and 29 are believed to be patentable over the cited references, claims 4, 13, 22, and 31 are patentable in their current form.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles, California telephone number (213) 337-6700 to discuss the steps necessary for placing the application in condition for allowance.

Application Serial No. 10/010,005 Customer No.: 26021 PATENT 2036-039 (81841.0177)

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1314.

Respectfully submitted, HOGAN & HARTSON L.L.P.

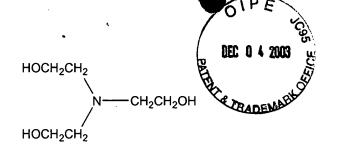
Dated: December 2, 2003

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triethanolamine

trimethanolamine

$$\begin{array}{c} \text{HOCH}_2\text{CH}_2\\ \\ \text{N----}\text{CH}_2\text{CH}_2\text{CH}_2\text{CH}_3\\ \\ \text{HOCH}_2\text{CH}_2\\ \end{array}$$

N-butyldiethanolamine

3-dimethylamino-2-methylpropyl chloride

N,N-dimethylglycine

$$\begin{array}{c} \text{CH}_3 \\ \text{N} \longrightarrow \begin{array}{c} \text{CHNH}_2 \\ \text{NH}_3 \end{array}$$

N,N-dimethylguanidine

$$CH_3$$
 N
 $CH_2COCH_2CH_3$
 CH_3
 O

N,N-dimethylglycine ethyl ester

$$CH_3$$
 N
 CH_2CH_2C
 CH_3

3-dimethylaminopropionitrile

N,N-diethylacetamide

$$CH_3$$
 N
 CH_2CHCH_3
 CH_3
 NH_2

1-dimethylamino-2-propylamine